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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/380,200	01/30/1995	MAX L. BIRNSTIEL	0652.1080001	5449

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01/23/2003

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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/380,200

Applicant(s)
Birnstiel

Examiner
Patrick J. Nolan

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 35-42 is/are pending in the application.
- 4a) Of the above, claim(s) 3-7, 11, 12, 15, 16, 21-27, 30-33, 35, 37, and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8-10, 13, 14, 17-20, 28, 29, 36, and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 56+59 6) ☐ Other:

Part III DETAILED ACTION

1. This application is a continuation of 07/946,498.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-6-02 has been entered.
3. Claims 1-33 and 35-42 are pending.
4. Claims 3-7, 11-12, 15-16, 21-27, 30-33, 35, 37 and 42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1, 2, 8, 13, 14, 17-20, 28, 36, 38-41 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,144,019, of record, in view of U.S. Patent 5,166,320 and U.S. Patent 5,428,132.

The '019 patent teaches targeting HIV infected T cells with liposomes carrying ribozymes.

The claimed invention differs from the prior art by using antibody-polycation-ribozyme conjugates to target T cells for treating HIV.

However, the '320 patent specifically teaches that liposome polynucleotide delivery systems are problematic because there has been difficulty in directing cell type specificity (column 1, lines 50-52 in particular). The '320 patent teaches overcoming this problem by creating a polynucleotide delivery system that links the polynucleotide of interest to a polycation and then links the polycation to a specific cell receptor binding ligand, such as an antibody. The '132 patent teaches targeting T cells by using an antibody to CD3 (see column 4, lines 45-48 in particular).

Therefore one of skill in the art at the time the invention was made would have been motivated to substitute the liposome-ribozyme delivery system taught by the '019 patent to infect HIV infected T cells with an antibody polycation polynucleotide delivery system taught by the '320 because the antibody polycation polynucleotide delivery systems have cell specificity while liposome-polynucleotide conjugate do not. Furthermore, it would have been obvious to use the anti-CD3 antibodies taught by the '132 patent, since anti-CD3 antibodies specifically target T cells and said anti-CD3 antibodies are specifically taken up by T cells.

Since the rejection has been set forth in a different order of references and for different reasoning. Applicant's arguments are not considered.

6. Claims 1, 2, 8-10 13, 14, 17-20, 28-29, 36, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no written support for the sub-genus of the protein component of the conjugate is capable of binding to a cell surface protein other than a transferrin receptor in the originally filed claims or specification. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 8:30 to 4:30 pm.

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8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Pat J. Nolan

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
January 17, 2003